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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,941	03/10/2004	Ruud Philip Antoon Maria Segers	I-1997.267 US D2	6641
31846	7590	02/23/2006	EXAMINER	
INTERVET INC. PATENT DEPARTMENT PO BOX 318 MILLSBORO, DE 19966-0318			HINES, JANA A	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/798,941

Applicant(s)

SEGRS ET AL.

Examiner

Ja-Na Hines

Art Unit

1645

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 November 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 20.

Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____

13. ☐ Other: _____.


**LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**

The proposed amendments filed after a final rejection will not be entered because they raise new issues that would require further search and consideration. The new issues are drawn to the nucleotide sequence comprising the promoter region of the ApxIV gene from position 594 to 641 of SEQ ID NO:5 and a heterologous gene that is functionally linked to the promoter region. This would require a new search, because the previous claims were not drawn to the promoter region and a functionally linked heterologous gene. Moreover, Applicants point to support at page 9, lines 16-25 which is drawn to expression of the heterologous gene. However the amended claims no longer require the isolation of the sequence, thus the sequence is a product of nature, yet the heterologous gene can only be linked by replacement or certain nucleic acids or be recombinantly expressed as a fusion construct. Therefore applicants' after final amendments do not place the application in better form for appeal by materially reducing or simplifying the issues for appeal. Thus the after final amendment will not be entered.

Applicants' arguments with respect to claim 20 has been considered but are moot in view of the maintaining of the previous grounds of rejection.

The written description rejection of claim 20 under 35 U.S.C. 112, first paragraph is maintained for reasons of record. The issues about the claim using comprising language is that the claims do not define what the nucleotides at either end of the sequence are. Therefore, the rejection is not a per se prohibition on having an open claim; rather the rejection is that these nucleotides are not defined. The specification refers to SEQ ID NO:5, however the specification provides no guidance as to what other nucleotides may be encompassed by the claimed nucleotide sequence. Moreover, the claim recites open language and therefore includes a wide variety and unlimited number of additional nucleotides. Yet there is no disclosure of how many of these other nucleotides may be present. The claim fails to limit the number of additional nucleotides within the sequence yet recites that the nucleotide sequence which must only comprise nucleotides 594 to 641 of SEQ ID NO:5. Therefore all sequences having the same nucleotides as those with positions 594 to 641 of SEQ ID NO:5 are being claimed, along with all other possible combinations of nucleotides. There is no specific limitation for what additional nucleotides may be included. However the unlimited additions have not been taught and/or enabled by the specification.

Thus, the nucleotide sequence harboring the promoter controlling the expression of the *A. pleuropneumoniae* RTX-operon type IV (Apx IV) gene, characterized in that said nucleotide sequence comprises the DNA fragment from position 594 to 641 of SEQ ID NO:5 fails to meet the written description provision of 35 USC 112, first paragraph.

Contrary to applicants assertions, there is no requirement limiting the claim, the requirement is to define what is encompassed by the claim. Thus, the structure of the entire nucleotide sequence is not defined. Even though claim 20 recites that the sequence must comprise at least positions 594 to 641 of SEQ ID NO:5, the claim does not limit the number of other nucleotides that may be included in the sequence. Therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method for production. Thus it appears that applicants have not defined those additional nucleotides, therefore the rejection is maintained.

The rejection of claim 20 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 20 is drawn to a sequence that naturally occurs. Moreover, the open claim language allows the sequence to comprise more than just nucleotides 594 to 614 of SEQ ID NO:5, the claimed sequence has no limit and can therefore be the entire genome. Furthermore, Dreyfus et al., (2004) teach that ApxIV is expressed by all serotypes of *Actinobacillus pleuropneumoniae* (*A. pleuropneumoniae*) after infection of pigs (page 228). Thus, any pig with an *A. pleuropneumoniae* infection inherently comprises a nucleotide sequence harboring the promoter controlling the expression of the *apxIV* gene. Moreover, positions 594 to 641 of SEQ ID NO:5 are the same nucleotides as those from the wild-type strain, thus, the nucleotide sequence naturally occurs. For example, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. The claimed sequence has no markedly different characteristics than any found in nature, therefore, the claims are drawn to non-statutory subject matter and not entitled to patent protection. Thus applicants arguments are not persuasive and the rejection is maintained.